

10/593659  
IAP9/Rec'd PCT/PTO 21 SEP 2009

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James Hardwick et al.

Serial No. to be assigned

Filed:

For: Method and Biomarkers for Detecting Tumor Endothelial  
Cell Proliferation

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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DATE OF DEPOSIT September 21, 2009  
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

**MERCK & CO., INC.**

By \_\_\_\_\_ Date \_\_\_\_\_

## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

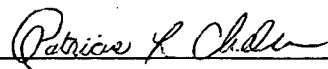
| RELATED APPLICATION |             |            |
|---------------------|-------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
|                     |             |            |
|                     |             |            |
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|                     |             |            |

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

  
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 Date: 9/20/2006

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|---|---|----|--------------------------|---------------------------------|---------|
| Substitute for form 1449B/PTO<br><b>INFORMATION DISCLOSURE</b><br><br><b>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |   |    | <b>COMPLETE IF KNOWN</b> |                                 |         |
|   |   |    | Application Number       | to be assigned <b>10/593659</b> |         |
|   |   |    | Filing Date              | <b>10/593659</b>                |         |
|   |   |    | First Named Inventor     | Hardwick et al.                 |         |
|   |   |    | Group Art Unit           |                                 |         |
|   |   |    | Examiner Name            |                                 |         |
| Sheet   | 2 | of | 3                        | Attorney Docket Number          | 21412YP |

| NON PATENT LITERATURE DOCUMENTS |          |  |
|---------------------------------|----------|--|
| Examiner Initials*              | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.   |
| T.W.                            | AA       | Abe et al. "cDNA Microarray Analysis of the Gene Expression Profile... Umbilical Vein Endothelial Cells", Angiogenesis, Vol. 4, 289-298 (2001)   |
|                                 | AB       | DiPrimo et al. "Expression Profiling of Blood Samples...Strategy for Biomarker Identification", BMC Cancer, 3:3, 1-12 (February 7, 2003)   |
|                                 | AC       | Gerritsen et al. "In Silico Data Filtering to Identify New Angiogenesis..Profiling Data Set", Physical Genomics, Vol. 10, 13-20 (2002)   |
|                                 | AD       | Hardwick et al. "Identification of Biomarkers for Tumor Endothelial Cell... Expression Profiling", Molecular Cancer Therapeutics, 4(3), 413-425 (March 2005)   |
|                                 | AE       | Ho et al. "Identification of Endothelial Cell Genes by Combined Database Mining and Microarray Analysis", Physiol. Genomics, Vol. 13, 249-252 (2003)   |
|                                 | AF       | Jones et al. "Molecules in Focus: Clusterin", International Journal of Biochemistry & Cell Biol. Vol. 34, 427-431 (May 2002)   |
|                                 | AG       | Kikuchi et al. "Decreased ETB Receptor Expression in Human Metastatic Melanoma Cells", Biochemical and Biophysical Research Communications, Vol. 219, 734-739 (February 1996)  |
|                                 | AH       | Lee et al., "Molecular Cloning and Characterization of a Murine LPS-Inducible cDNA", J. Immunology, Vol. 152, 5758-5767 (June 1994)  |
|                                 | AI       | Lahav et al. "An Endothelin Receptor B Antagonist... Melanoma Cells In Vitro and In Vivo", Proc. Natl. Acad. Sci. USA, Vol 96, pp 11496-11500 (September 1999)   |
|                                 | AJ       | Lauren et al. "Is Angiopoietin-2 Necessary for the Initiation of Tumor Angiogenesis?", American Journal of Pathology, Vol 153, 1333-1339 (November 1998)   |
|                                 | AK       | Mazar et al. "The Urokinase Plasminogen Activator System in Cancer: Implications for Tumor Angiogenesis and Metastasis", Angiogenesis, Vol. 3, 15-32 (1999)  |
|                                 | AL       | Smith et al. "The Glucocorticoid Attenuated Response Genes GARG-16, GARG-39, and GARG-49/IRG2... Tetratricopeptide Repeat Domains", Archives of Biochemistry and Biophysics, Vol 330, No. 2, 290-300 (June 15, 1996) |
|                                 | AM       | Staton et al. "Current Methods for Assaying Angiogenesis In Vitro and In Vivo", Int. J. Exp. Path., Voll. 85, 223-248 (2004)   |
|                                 | AN       | Taniguchi et al., "Expression and Transcriptional Regulation of the Human Alpha 1,3-Fucosyltransferase 4(FUT 4)... Cell Lines", Biochemical and Biophysical Research Communications, Vol. 273, 370-376 (2000)        |
| ↓                               | AO       | Withers et al. "Human Alpha(1,3)-fucosyltransferase IV (FUTIV).. in the U937 Cell Line", The Journal of Biological Chemistry, Vol. 275, 40588-40593 (December 22, 2000)  |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

*(use as many sheets as necessary)*

**COMPLETE IF KNOWN**

|                        |                 |
|------------------------|-----------------|
| Application Number     | to be assigned  |
| Filing Date            | 10/5/93         |
| First Named Inventor   | Hardwick et al. |
| Group Art Unit         |                 |
| Examiner Name          |                 |
| Attorney Docket Number | 21412YP         |

|       |   |    |   |
|-------|---|----|---|
| Sheet | 2 | of | 3 |
|-------|---|----|---|

## NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.  |
|--------------------|----------|---|
| T.W.               | AP       | Zhang et al. "Tumor-Derived Vascular Endothelial Growth Factor... Supporting Angiogenesis in Ovarian Cancer", Cancer Res. 63, 3403-12 (June 1003) |

**Examiner  
Signature**

/Teresa Wessendorf/

Date  
Considered

07/19/2010

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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